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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,149	08/08/2003	Gerald E. McDonnell	MEDZ 2 01304	3426

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
03/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/637,149	MCDONNELL ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 22-30* is/are pending in the application.

4a) Of the above claim(s) *2-4 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-13,15-18 and 22-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/9/2009 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-13, 15-18 and 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 7252720 (hereinafter as "Foster"), Ernst and Race

(1993, previously cited) and US Patent Application 10/467591 (hereinafter as "Kritzler", previously cited).

Foster describes the removal of prion infectivity (see whole document). The authors provide that the use of concentrated solutions of salts, such as sodium chloride, is effective in both eluting and completely removing adsorbed prion infectivity (see Summary of the Invention, column 2). The authors further describe a method of cleaning a reusable substrate via washing the substrate with a salt solution of a concentration of at least 1.0 M (see column 3). Note that the author describes both medical and surgical instruments and further describes known cases of contaminated electrodes which have lead to the transmission of CJD. This meets the limitation of a medical device; see claim 11. This reference does not teach the use of either a phenol or a sulfonate.

Ernst and Race teach a method in which the scrapie agent of brain homogenates is inactivated following treatment with LpH, or an aqueous phenolic disinfectant comprising both o-phenylphenol and o-benzyl-p-chlorophenol (see page 196). Because the prion is *inactivated*, the limitation of "a change in the three dimensional structure of the prion protein" has been met; see claim 1. Note that [0048] of the instant specification provides that OPP is not halogenated and this meets the limitation of claim 11; see phrase "a composition comprising a non-halogenated phenol. While this reference teaches using a concentration of 90% of LpH (page 197) which equates to 9% of phenolic derivative concentration (see 198 for conversion), varying the phenolic concentration would have been obvious to one of ordinary skill in the art in

order to achieve optimal results of prion inactivation. Of note, the partition coefficient is dependent on the concentration value. The references above, however, do not teach a method using a composition that further comprises dodecylbenzene sulphonic acid.

Kritzler et al teach a method and a composition for treating a surface contaminated with a scrapie prion protein. The composition comprises one or more agents which favor the conformational unfolding of a scrapie prion protein (see Abstract), including inorganic salts and surfactants (see paragraphs 41 and 42). Dodecyl benzene sulfonate is disclosed in paragraph 41 as a denaturant that tends to "bind to proteins and initiate unfolding of tertiary structure". According to the instant specification, dodecylbenzene sulphonic acid can be used as either a surfactant or as an acidic sequester agent. Further, Kritzler et al describe the use of a cosolvent, including m-Cresol (paragraph 39). A cosolvent is defined by the instant specification in paragraph 45 and includes a polyol which comprises only carbon, hydrogen and oxygen atoms. M-Cresol meets this definition. Kritzler et al disclose that such solvents "tend to denature, dissolve or swell proteins. “Generally the products are not completely unfolded and possess an ordered conformation which differs from the native state" (paragraph 39).

Thus, it would have been obvious for one of ordinary skill in the art to combine the references above and treat a substrate with high concentrations of salt, phenols, and sulfonates combined with a cosolvent. It would have been obvious for one of ordinary skill in the art to alter concentrations of each of the above elements in order to achieve optimal results. One would have been motivated to combine the elements in

order to effectively inactivate prion infectivity and remove such proteins from medical substrates. There would have been a reasonable expectation of success given the taught success of each of the applied references in inactivating prion proteins and removing prions from a substrate. Further, Kritzler provide teachings known chemicals and their function in protein chemistry. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. See MPEP 2144.06.

Response to Arguments

Applicant's arguments filed 2/9/2009 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Briefly, Applicant fails to combine the teachings. In response to this, each reference will be addressed along with Applicant's arguments. Ernst and Race teach the inactivation of scrapie prions using a composition of phenols. Note that Applicant acknowledge this to be the case in the recitation "The results showed a dramatic difference in inactivation between LpH and LpH-SE, with LpH being 10^4-10^5 times more effective than LpH-SE". See p. 9-10 of REMARKS. Additionally, Applicant continuously point out that the LpH formulation includes a halogenated phenol. Applicant is reminded

that claim 10 is drawn (in part) to a composition *comprising* a non-halogenated phenol and given this claim language, may include a halogenated phenol. To sum, the ordinary artisan would have been motivated to use the taught composition in order to inactivate prions as successfully shown and as acknowledged by Applicant.

Foster teaches using salt to clean a substrate, including a medical or surgical instrument for reuse. Applicant acknowledges this teaching; see p. 9 of REMARKS. The ordinary artisan would be motivated to remove protein debris from an instrument before reusing it, particularly on a patient.

Kritzler describes a method of treating a contaminated surface using one or more agents that favor conformational unfolding (denaturing) to the infectious prion conformation. Examples include dodecyl benzene sulfonate and m-Cresol. While Applicant provides that Kritzler merely describes the effects of these agents to proteins in general and the teachings are not enabling to the infectious prion protein, Applicant is reminded that use of the agents is still a conceived invention of the prior art. The motivation of optimizing conformational unfolding is clear and the ordinary artisan would know how to use the agents. Given they are known to be protein unfolding agents one would expect that their effects coupled with that of LpH would be additive leading to potentiated results. Applicant fails to provide a reasonable explanation in view of these agents as to why such a combination would not specifically work for the infectious prion protein in view of the ordinary artisan. Lastly, it is not clear how the instant specification itself is enabling for such a broad scope of sulphonic acids, sulfonates and

combinations thereof in view of Applicant's own argument and Applicant is invited to respond to this.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/
Examiner, Art Unit 1648
/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648